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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,677	06/05/2006	Georgina Jane Clark	DAVI257.001APC	3961

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

NOTIFICATION DATE	DELIVERY MODE
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03/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/536,677	Applicant(s) CLARK ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 11-14 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/6</u> . | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment. one page.</u> |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group XVI, polypeptides of SEQ ID NO: 6, in the reply filed on January 14, 2008 is acknowledged. Applicant traverses the requirement "insofar as it requires restriction between Group XVI (e.g., an isolated polypeptide comprising an amino acid sequence of SEQ ID NO: 6) and Group XXII (e.g., antibodies specifically binding to an isolated polypeptide comprising an amino acid sequence of SEQ ID NO: 6). The Restriction Requirement is believed to be improper because, according to MPEP 803, there are two criteria for a proper Restriction Requirement: (A) The inventions must be independent or distinct as claimed, and (B) there would be a serious burden on the examiner if restriction is not required. Since Claims 11-14 are directed to antibodies that specifically bind the polypeptides of Claim 6, no significant, additional burden would be placed on the Examiner to examine these claims" (p. 4 of the Response). This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). The Examiner has shown that the Groups XVI and XXII are independent or distinct for the reasons in the previous Office action. Specifically, Inventions XVI and XXII, directed to polypeptides and antibodies respectively, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. Furthermore, in this case, the polypeptides of Group XVI are structurally unrelated large molecules which contain potentially hundreds of regions to which an antibody can bind, whereas the antibody of Group XXII is defined in terms of its binding specificity to a small structure within the disclosed SEQ ID NO.

The requirement is still deemed proper and is therefore made FINAL.

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2. Applicant's request to rejoin claim 27 directed to a composition comprising the polypeptide of SEQ ID NO: 6 with the elected claim 6 has been found to be persuasive.

3. Claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 14, 2008.

4. Claims 6 and 27 are under examination in the instant office action.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at p. 12 line 19. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Information Disclosure Statement

6. The information disclosure statement filed on June 22, 2006 fails to comply with 37 CFR 1.98 (b)(5), which require the following:

(b)(5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

In the instant case, the citation of the references is objected to because they contain embedded hyperlinks and/or other form of browser-executable code.

The information disclosure statement filed on June 22, 2006 has been considered in part (See MPEP § 609).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 6 and 27 are directed to polypeptides comprising SEQ ID NO: 6, derivatives, analogs, homologs of SEQ ID NO: 6 as well as polypeptides with a limited 70% identity to the polypeptide of SEQ ID NO: 6 and compositions thereof. The specification provides the description of the structure of the polypeptide of SEQ ID NO: 6 but provides no guidance as how to use the claimed molecules, thus, requiring undue experimentation on part of one skilled in the art to discover how to practice Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

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predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

It is clear from the instant application that the protein of SEQ ID NO: 6 described therein and designated 35-L1 or h35L-1 (Fig. 13 at p. 11, also pp. 5-6 of the instant specification) is what is termed an “orphan protein” in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. The specification states at pp. 1-2 that the molecules described in the instant application belong to “[t]he Immunoregulatory Signalling (IRS) family [which is] a group of cell surface molecules which regulate leukocyte function by delivering signals to the cells on which they are expressed. Members of the IRS family are typically either Immunoglobulin gene superfamily members or C-type lectins”. More specifically, the instant claimed polypeptide of SEQ ID NO: 6 is known as 35-L1 and belongs to the 35 LM family of proteins (page 7). The instant specification does not provide any information regarding the biological significance of this specific encoded protein, 35-L1 of SEQ ID NO: 6 or its role with respect to a specific physiological or pathological process. However, the specification asserts that the claimed polypeptide is useful to diagnose and/or treat the diseases and disorders listed in alphabetic order at pp. 46-110. The data to support this assertion are limited to the statement presented at p. 121 that,

“AML sample #14 stained positive for both 35-L3 and 35-L1 (see Figure 13) and AML sample #16 tested positive for 35-L3 and 35-L5 (see Figure 14).

These findings demonstrate that 35-L1, 35-L3 and 35-L5 are useful molecules for the diagnosis and treatment of AML infection in a subject”.

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While the skill level in the art is high, the level of predictability is low. The sole working examples in the specification, as originally filed, pertain to the staining of the blood cells obtained from a mouse model for AML with an antibody to 35-L1. The data presented within Figure 13, “a graphical representation demonstrating the cell surface expression of 35-L3 and 35-L1 on AML cells. Flow cytometric analysis demonstrated that a population of AML cells from sample #14 stained positive for 35-L3 and/or 35L-1 35-L1” do not allow a skilled practitioner to use the instant claimed polypeptides neither for diagnosis of AML nor for treatment of the disease. While it is not necessary that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding, no extrapolation can be made of what appears to be a single data point of the results of histological staining of the mouse cells for expression profile to support the asserted utility of the claimed molecules for treatment and/or diagnosis of human disease.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that:

“[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable” and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art”, “[i]t is the specification, not the knowledge of one

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skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”.

The instant specification is not enabling because one cannot follow the guidance presented therein and practice the claimed method without first making a substantial inventive contribution.

9. Claims 6 and 27 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6 and 27 are directed to polypeptides having at least 70% sequence identity with a particular disclosed sequence, derivatives, homologs, analogs, chemical equivalents and mimetics of the polypeptide of SEQ ID NO: 6. The claims do not require that the polypeptides possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity. However, the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a protein which has the amino acid sequence of SEQ ID NO: 6. The claims, however, are drawn to polypeptides having at least 70% sequence identity with a particular disclosed sequence, derivatives, homologs, analogs, chemical equivalents and mimetics of the polypeptide of SEQ ID NO: 6. Thus, the claims are not limited to a protein with

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a specific amino acid sequence. The claims only require the claimed polypeptides to share some degree of structural similarity to the isolated protein of SEQ ID NO: 6. The specification only describes a protein having the amino acid sequence of SEQ ID NO: 6 and fails to teach or describe any other protein which lacks the amino acid sequence of SEQ ID NO: 6 and has any relevance to the isolated protein 35-L1 of SEQ ID NO: 6.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. As stated above, it is not even clear what region of the encoded polypeptide has the disclosed activity. The specification does not provide a complete structure of those polypeptides having at least 70% sequence identity with a particular disclosed sequence, derivatives, homologs, analogs, chemical equivalents and mimetics of the polypeptide of SEQ ID NO: 6 and fails to provide a representative number of species for the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry,

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whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 6, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 6 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sweet et al., 1999, EP0909237A2.

Claims 6 and 27 are directed to the isolated polypeptide of SEQ ID NO: 6 and compositions thereof. Document of Sweet et al. teaches human PIGR-2 protein, which has 100% sequence identity to the instant polypeptide of SEQ ID NO: 6, and compositions thereof, see sequence alignment, and Sweet et al. document at sections [0047] and [052], for example.

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

March 07, 2008

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649